DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier R. VEDESMA

[Docket No. 2001D–0584]

"Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components (Including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of Human Immunodeficiency Virus Type 1 and Hepatitis C Virus;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components (Including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV," dated October 2004. The guidance provides recommendations to all establishments that manufacture Whole Blood and blood components (including Source Plasma and Source Leukocytes) on the implementation of licensed nucleic acid tests (NAT) to identify human immunodeficiency virus type 1 (HIV–1) ribonucleic acid (RNA), and hepatitis C virus (HCV) RNA in donations of Whole Blood and blood components to reduce the risk of transmission of these agents; and the reporting to FDA of such implementation. The guidance announced in this notice finalizes the draft guidances entitled "Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors

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to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV," dated December 2001 and "Use of Nucleic Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV," dated March 2002.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From

Donors of Whole Blood and Blood Components to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV," dated October 2004. FDA's final rule (66 FR 31146, June 11, 2001) entitled "Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Diseases" became effective on December 10, 2001. The regulations under § 610.40(b) (21 CFR 610.40(b)) require that establishments that collect or manufacture Whole Blood and blood components "must perform one or more screening tests to adequately and appropriately reduce the risk of transmission of communicable disease agents" (66 FR 31146 at 31162). As we noted in the preamble to the final rule, the standard for adequate and appropriate testing will change as new testing technology is approved by FDA. We explained, "* * * we intend to regularly issue guidance describing those tests that we believe would adequately and appropriately reduce the risk of transmission of communicable disease agents" (66 FR 31146 at 31149).

The guidance announced in this notice finalizes the draft guidances entitled "Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV," dated December 2001, and "Use of Nucleic Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV," dated March 2002. This guidance recommends that establishments implement these recommendations as soon as feasible, but not later than 6 months after publication of this notice.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or

on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 601.12 and § 610.40 of this guidance were approved under OMB control numbers 0910–0315 and 0910–0472.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: 10/20/04

October 20, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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